

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC.,

Plaintiff,

vs.

Civil Action No. 5:23-cv-00626-XR

BRAIN FREQUENCY LLC,

Defendant.

Demand for Jury Trial

**DEFENDANT BRAIN FREQUENCY LLC’S REPLY IN SUPPORT OF ITS MOTION
FOR PARTIAL SUMMARY JUDGEMENT PURSUANT TO THE PHYSICIAN’S
IMMUNITY STATUTE**

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and the Court’s Local Rules, Defendant Brain Frequency LLC (“Brain Frequency”) hereby files its Reply in Support of its Partial Motion for Summary Judgment pursuant the Physician’s Immunity Statute (Dkt. No. 30) (“Motion”). In support thereof, Brain Frequency would respectfully show the Court as follows:

I. INTRODUCTION

The purpose of the Physician’s Immunity Statute is to protect companies like Brain Frequency from claims of patent infringement. The policy is obvious: companies whose primary goal is improving *methods and procedures* to assist medical practitioners to better diagnose and treat patients are afforded the opportunity to innovate without disruptive lawsuits such as this one.¹

¹ As noted herein, the statute’s exceptions to immunity serve to prevent pharmaceutical companies, device manufacturers and non-physician laboratories from seeking immunity. Brain Frequency is not a pharmaceutical company, a device manufacturer, or a non-physician laboratory—it provides only services to assist medical practitioners.

In its Motion, Brain Frequency demonstrated beyond any reasonable dispute that it is entitled to immunity as to all *method claims* asserted against it pursuant to the Physician's Immunity Statute. In its response, Wave Neuroscience LLC ("Plaintiff") does not attempt to dispute the overwhelming majority of the undisputed material facts cited in Defendant's Motion supporting that conclusion. Instead, Plaintiff contends immunity does not apply because (1) Brain Frequency is not a "related health care entity," and (2) Brain Frequency has engaged in "commercialization" of a machine or device that precludes the protection of the statute. Plaintiff is incorrect on both counts. With regard to the former, Brain Frequency squarely meets the definition of "health care entity" under the law of this circuit. With regard to the latter, Brain Frequency *does not commercialize* anything, much less a machine or device – it only sells software.

Accordingly, for the reasons set forth herein and in Defendant's Motion, immunity applies to all method claims asserted against Brain Frequency, and thus Defendant's summary judgment motion should be granted in its entirety.

II. ARGUMENT

A. Brain Frequency is a "Related Health Care Entity"

Plaintiff contends Brain Frequency is not a "related health care entity" because (1) it is not a "healthcare facility" at which a "medical activity is performed," and (2) it does not provide medical treatments "directly" to patients. [See Plaintiff's Response to Brain Frequency's Partial Motion for Summary Judgment (Dkt. No. 33) ("Pl. Resp.") at 6-11.] In other words, according to Plaintiff, because Brain Frequency does not diagnose patients or provide treatments directly, it cannot be a "related health care entity." [*Id.* at 9.] Not only do these assertions run afoul of the plain language of the Physician's Immunity Statute by adding requirements that *do not exist*, those

exact assertions were expressly rejected in *Emtel, Inc. v. Lipidlabs, Inc.* 583 F. Supp. 2d 811 (S.D. Tex. 2008)

First, as for the Physician’s Immunity Statute itself, Section 287(c)(1) provides as follows:

With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against ***a related health care entity*** with respect to such medical activity.

35 U.S.C. § 287(c)(1). Section 287(c)(2)(C) then broadly defines a “related healthcare entity” as “an entity with which a medical practitioner has a *professional affiliation* under which the medical practitioner performs the medical activity” 35 U.S.C. § 287(c)(2)(C) (emphasis added). As used in Section 287(c)(2)(C), the term “professional affiliation” broadly includes “staff membership, . . . ***contractual relationship***, . . . or ***other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with***, the health care entity.” 35 U.S.C. § 287(c)(2)(D) (emphasis added). Nowhere in the plain language of the statute does it require that the “related healthcare entity” ***be an actual healthcare facility itself***, nor does the statute require that a related healthcare entity “directly” provide medical treatments. Instead, it simply requires that a “related healthcare entity” facilitate medical activities on medical patients by medical practitioners, which is precisely what Brain Frequency does. [See Def. Mot. at 4-5, 8-9.]

This is the conclusion reached in *Emtel*. There, the movants accused of infringement were *not* “healthcare” facilities themselves, nor did they provide medical treatment “directly” to patients. Instead, they merely provided “business, administrative, and technological support to their affiliated physicians,” as well as “videoconferencing equipment.” *Emtel*, 583 F. Supp. at 817 (noting that the physicians were “independent contractors who exercised independent judgment

and maintain discretion over the medical care they provided to patients”). Even though movants did not provide the actual medical treatment or diagnosis themselves, their agreements and relationships with independent contractor physicians nevertheless qualified them as “related health care entities.”² *Emtel*, 583 F. Supp. at 824-25. The same is true here. [Def. Mot. at 8-9.]

Indeed, the circumstances in *Emtel* are indistinguishable from the facts of this case, save one: the companies in *Emtel* did not develop actual *medical methods or procedures* that allowed medical practitioners to better diagnose and treat patients. Brain Frequency *does*. If the defendants in *Emtel* who merely provided computer/phone technology to medical professionals clearly fell within the definition of “related health care entity,” there can be no dispute that Brain Frequency does as well. *See Emtel*, 583 F. Supp. at 817-818, 824-825; *see also* Def. Mot. at 8-9 (demonstrating that Brain Frequency developed improved methods and procedures for diagnosing and treating patients and that those methods and procedures are applied directly to patients by medical practitioners via contractual arrangements with Brain Frequency).

B. The Limited Exemptions Precluding Application of Immunity Under Section 287(c) Do Not Apply to Brain Frequency

As noted in Brain Frequency’s Motion, Section 271(c) does not apply if the medical activity is (1) ***directly related to the commercial development***, manufacture, sale, importation, or distribution of ***a machine***, and (2) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act. 35 U.S.C. § 287(c)(3). In its Response, Plaintiff contends the exemption somehow applies because (1) Brain Frequency’s

² Plaintiff’s argument that Brain Frequency’s arrangement with its medical practitioners disclaims providing medical advice is also unavailing. Notably, similar language between the movants and the physicians in *Emtel* did not affect the Court’s analysis of the application of the Physician’s Immunity Statute. *Emtel*, 583 F. Supp. at 838. (noting that the agreements with the physicians “set some basic parameters for the physicians—including adhering to professional standards, maintaining liability insurance, complying with schedules, using certain billing services—but *do not set limits on or assert control over the physicians’ medical work judgment, or skill.*”).

Software requires *use* of a device regulated by the Federal Food, Drug, and Cosmetic Act, and (2) Brain Frequency’s activities clearly relate to the “commercialization” of such devices. [See Pl. Resp. at 11-14.] Both contentions are wrong.

As to the first contention—use of an FDCA regulated machine—Plaintiff misses the mark. Indeed, the statute *does not* state that procedures that require use of a “machine” are exempted from immunity. Instead, it states, in relevant part:

[The immunity] . . . does not apply to the activities of any person . . . who is engaged in the commercial development, manufacture, sale, importation, or distribution *of a machine* . . . where such activities are: (A) *directly related to the commercial development, manufacture, sale, importation, or distribution of a machine*

See 35 U.S.C. § 287(c)(1) (emphasis added). This exemption *was not intended* to exclude the medical activities (methods and procedures) facilitated by medical practitioners directly on patients, for example, via Brain Frequency’s Software. Instead, the “exception serves to prevent pharmaceuticals, *device manufacturers* and non-physician laboratories from invoking the provisions of the statute,” as such companies that primarily endeavor to sell products or drugs. See Leisa Talbert Peschel, Ph.D, *Revisiting the Compromise of 35 U.S.C. S 287(c)*, 16 TEX. INTELL. PROP. L.J. 299, 311 (2008) (emphasis added). Brain Frequency is not a pharmaceutical company or a non-physician laboratory, nor is it a *device manufacturer* “who is engaged in the *commercial development*, manufacture, sale, importation, or distribution *of a machine* . . .” [Def. Mot. at 10-12; see also *id.*, Malish Decl. (Dkt. No. 30-2) at ¶¶ 10-14.] Accordingly, the exemption does not apply.³

Plaintiff’s next contention—that Brain Frequency’s specific activities are “*commercial*”

³ To the extent Plaintiff believes certain FDCA regulated devices infringe its patents, that is an issue that should be taken up with the manufacturers of those products. Whether those devices infringe or not is irrelevant to whether the specific activities and procedures facilitated by Brain Frequency’s Software alleged to infringe Plaintiff’s asserted *method* claims are protected medical activities under the Physician’s Immunity Statute.

activities related to the sale of a “device”—is also unavailing. In particular, Plaintiff argues that (1) Brain Frequency offers to lease certain devices to doctors needed to use the Brain Frequency Software via its contracts; (2) Brain Frequency promoted use of a device on a podcast and offered discounts for the service; and (3) Brain Frequency’s founder, Shannon Malish, has suggested that patients seek diagnosis and treatment using the Brain Frequency Software every few years and that she plans to do so herself when she turns a certain age. [See Pl. Resp. at 12-14.] These contentions are irrelevant, misleading and/or outright false.

As to Plaintiff’s first contention—references to products or devices in Brain Frequency’s license agreements—those contracts identify devices that *can* be used by doctors in conjunction with Brain Frequency Software. This is no different, for example, than Microsoft disclosing the minimum hardware requirements needed to run its Windows operating system—it recommends a computer to run the software, but not does not provide the computer itself. While there is language in the license agreement about leasing products, that language was left in extraneously, as Brain Frequency has never sold or leased any “device” pursuant to any agreement with medical practitioners and has no intention of doing so. [See Second Declaration of Shannon Malish (“2nd Malish Decl.”) filed herewith at ¶¶ 4-5.] Instead, the agreement makes clear that all medical practitioners are responsible for obtaining their own equipment and are fully responsible for using that equipment using their own medical judgment and expertise. [Def. Motion, Malish Decl., Ex. 5 at Sec. 4.1.] Brain Frequency has never leased, sold, or otherwise commercialized any device related to the Brain Frequency Software. [Def. Mot. at 10-12; *see also* 2nd Malish Decl. at ¶¶ 4-5.]

Plaintiff’s second contention—that Brain Frequency commercialized a product and offered product discounts during a podcast—is also incorrect. While Ms. Malish discussed certain devices

on the podcast referenced by Plaintiff, that discussion was in the context of discussing how to implement the Brain Frequency Software. At no point during the podcast did Ms. Malish discuss buying or selling devices or make any other comments related to the “commercialization” of same, and Plaintiff’s failure to cite to a *single timestamp* of any “commercial discussion” during that podcast confirms that fact. [Def. Mot. at 10-12; *see also id.*, Malish Decl. at ¶¶ 10-14; *see also* Pl. Resp. at 13 (failing to cite a single instance of Ms. Malish attempting to sell any devices or products).] Furthermore, Brain Frequency has never offered any “discount” for podcast listeners to any product or service, and Plaintiff’s suggestion otherwise is mistaken. [See 2nd Malish Decl. at ¶ 6 (noting that the promotion that Plaintiff cites was not by Brain Frequency).]

Finally, Plaintiff contends that Ms. Malish’s recommendation that certain people, including herself, could benefit from the Brain Frequency Software constitutes “commercialization.” [Pl. Resp. at 13.] This statement is nonsensical. As noted in Ms. Malish’s declaration, use of the Brain Frequency Software has broad benefits for many potential patients. [Def. Motion, Malish Decl., at ¶¶ 2-5.] That simple medical statement, which is true, does not constitute “commercialization” of anything, let alone commercialization of a machine or device excluded from protection under the Physician’s Immunity Statute.

In sum, Brain Frequency has engaged in no “commercial activities” *directly related* to the commercial development, manufacture, sale, importation, or distribution *of a machine*, nor has it ever sold or leased a machine or product with its software. [Def. Mot. at 10-12; *see also id.*, Malish Decl. at ¶¶ 10-14; 2nd Malish Decl. at ¶¶ 4-5.] Accordingly, Brain Frequency is entitled to the protection of the Physician’s Immunity Statute. *See* 35 U.S.C. § 287(c)(1).⁴

⁴ In its Response, Plaintiff relies on a single case as support for its position that Brain Frequency has engaged in “commercialization” of a device. [See Pl. Resp. at 13 (citing *Viveve, Inc. v. Thermigen, LLC*, 2017 WL 1425604 (E.D. Tex. Apr. 20, 2017)).] *Viveve* is easily distinguishable. In that case, the allegations against the defendants

C. The Remainder of Plaintiff’s Extraneous Contentions are Red Herrings

In addition to the arguments addressed above, Plaintiff raises several additional issues having *nothing* to do with the proper application of immunity that nevertheless must be addressed.

First, Plaintiff contends that Brain Frequency “does not attempt to argue [it] does not infringe [Plaintiff’s] patents.” [Pl. Resp. at 1.] That statement is false. Brain Frequency has vigorously disputed Plaintiff’s infringement allegations (and others) from the time it filed an answer in this case and continues to do so. With respect to its Motion regarding immunity, Brain Frequency merely asserted that Plaintiff’s *allegations* “constitute an infringement” under the Physician’s Immunity Statute and therefore immunity applies. *See Emtel*, 583 F. Supp. at 824-25 (explaining that to “constitute an infringement” such that immunity applies under the Physician’s Immunity Statute, each method claim *must relate to a medical activity*). Here, Brain Frequency demonstrated that all of Plaintiff’s asserted method claims relate to a “medical activity,” and therefore are immune. [See Def. Mot., Appx. A at ¶¶ 1-46.] Plaintiff cannot, and does not, deny this fact.⁵

Next, Plaintiff contends the Physician’s Immunity Statute is a “rarely-litigated area of law,” implying that it clearly doesn’t apply in this case. [Pl. Resp. at 5.] Plaintiff is correct that the Statute

involved both a procedure *and a device* developed by the defendants to implement certain procedures that the Court determined had been “commercialized” together on certain promotional appearances by the defendants. *See id.* at *3-5. Here, there are *no devices* that have been developed, manufactured, sold or otherwise “commercialized” by Brain Frequency, and therefore the exemption to immunity in 35 U.S.C. § 287(c)(1) does not apply.

⁵ Notably, Brain Frequency included a Separate Statement of Undisputed Materials Facts supporting its Motion for Summary Judgment. [See Dkt. No. 30. Appx. A.] In response, Plaintiff admits it makes no effort to dispute the facts set forth in paragraphs 1-46. [Pl. Resp. at 2, FN 1.] Accordingly, each of those facts are undisputed for the purposes of Defendant’s Motion, including that the claims Brain Frequency has moved to dismiss are all method claims; that each method claim relates to the performance of a medical activity or procedure on a body by a medical practitioner; and that neither Plaintiff’s Second Amended Complaint or Infringement Contentions contain any specific evidence or allegations of contributory infringement pursuant to Section 271(c). [See Def. Mot., Appx. A at ¶¶ 1-46.]; *see also* Fed. R. Civ. P. 56(e)(2); *Cano v. State Farm Mut. Auto. Ins. Co.*, 425 F. Supp. 3d 779, 784 (W.D. Tex. 2019) (noting that when the nonmoving party has failed “to address or respond to a fact raised by the moving party and supported by evidence, then the court may consider the fact as undisputed.”) (citing *Broadcast Music, Inc. v. Bentley*, Civil Action No. SA-16-CV-394-XR, 2017 WL 782932, at *2 (W.D. Tex. Feb. 28, 2017).

is rarely litigated. However, that is because most companies are not in the business of suing licensed social workers and companies founded by social workers (like Brain Frequency) whose primary goal is improving methods and procedures to assist medical practitioners to better diagnose and treat medical patients. [Def. Mot., Malish Decl. at ¶¶ 1-9.] Had Plaintiff not done that in this case, there would be no reason to invoke the Physician's Immunity Statute.

Finally, Plaintiff contends additional discovery is needed to fully address Brain Frequency's Motion. [Pl. Resp. at 14-15.] This is incorrect as well. As noted herein and Defendant's Motion, Brain Frequency is a "related health care entity," based on the undisputed record evidence. As to the immunity exemption, even if there was a material fact issue regarding whether Brain Frequency has engaged in "commercialization" in general (there is not), there is no reasonable dispute that Brain Frequency does not manufacture a "machine" or "device." [Def. Mot. at 10-12; *see also id.*, Malish Decl. at ¶¶ 10-14.] Accordingly, there are no fact issues precluding application of the Physician's Immunity Statute in this case and any additional discovery would not change the record evidence.

V. CONCLUSION

For the reasons set forth herein and in Defendant's Motion, Brain Frequency respectfully requests the Court grant summary judgment that Brain Frequency is immune from all liability related to the alleged infringement of all claims of the Asserted Method Claims asserted by Plaintiff as a matter of law.

Dated: May 31, 2024

Respectfully submitted,

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LLC**

CERTIFICATE OF SERVICE

This to certify that on this the 31st day of May 2024, a true and correct copy of the foregoing has been served upon counsel of record via authorized electronic service.

/s/ John Saba

John D. Saba, Jr.